specifications. Thus, the FAA finds it necessary to extend the SFAR until June 1, 1996.

Good Cause Justification for Immediate Adoption

The reasons which justify the adoption, and the subsequent revision, of SFAR 38 still exist. Therefore, it is in the public interest to establish a new termination date for SFAR 38–2 of June 1, 1996. If the FAA publishes a final rule adopting a new part 119 into the Federal Aviation Regulations before the termination date, that rulemaking will rescind SFAR 38–2. This action is necessary to permit continued operations under SFAR 38–2 and to avoid confusion in the administration of FAA regulations regarding operating certificates and operating requirements.

For this reason, and because this amendment continues in effect the provisions of a currently effective SFAR and imposes no additional burden on any person, I find that notice and public procedures are unnecessary, impracticable, and contrary to the public interest, and that the amendment should be made effective in less than 30 days after publication. However, interested persons are invited to submit such comments as they desire regarding this amendment. Communications should identify the docket number and be submitted in duplicate to the address above. All communications received on or before the close of the comment period will be considered by the Administrator, and this amendment may be changed in light of the comments received. All comments will be available, both before and after the closing date for comments, in the rules docket for examination by interested parties.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) was enacted to ensure that small entities are not unnecessarily and disproportionately burdened by Government regulations. The RFA requires agencies to review rules which may have ''a significant economic impact on a substantial number of small entities.''

This rule will not impose any additional incremental costs over those that would have been incurred when SFAR 38–2 was first issued. Therefore, I certify that the amendment will not have a significant economic impact on a substantial number of small entities.

International Trade Impact Analysis

The FAA finds this amendment will have no impact on international trade.

Paperwork Reduction Act

Information collection requirements in this SFAR have previously been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511) and have been assigned OMB Control Number 2120–0008.

Federalism Implications

The amendment herein would not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this amendment would not have sufficient federalism applications to warrant the preparation of a Federalism Assessment.

Conclusion

The FAA has determined that this document involves an amendment that imposes no additional burden on any person. Accordingly, it has been determined that this action is not significant under Executive Order 12866; it is not significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and the anticipated impact is so minimal that a full regulatory evaluation is not required.

List of Subjects

14 CFR Part 121

Air carrier, Aircraft, Airmen, Air transportation, Aviation safety.

14 CFR Part 125

Aircraft, Airmen, Airports, Airspace, Air traffic control, Air transportation, Chemicals, Children, Drugs, Flammable materials, Handicapped, Hazardous materials, Infants, Smoking.

14 CFR Part 127

Air carriers, Aircraft, Airmen, Airworthiness.

14 CFR Part 129

Air carriers, Aircraft, Airmen, Air transportation, Aviation safety, Safety.

14 CFR Part 135

Air carriers, Aircraft, Airmen, Air taxis, Air transportation, Airworthiness, Aviation safety, Safety.

Adoption of the Amendment

In consideration of the foregoing SFAR 38–2 (14 CFR parts 121, 125, 127, 129, and 135) of the Federal Aviation Regulations is amended as follows:

PART 121—[AMENDED]

1. The authority citation for part 121 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40101, 40105, 40113, 44701–44702, and 44704–44705.

PART 125—[AMENDED]

2. The authority citation for part 125 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 1153, 40101, 40105, 44113, 44701–44705, 44707–44714, 44716–44717, and 44722.

PART 127—[AMENDED]

3. The authority citation for part 127 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44705, 44710–44711, and 44713.

PART 129—[AMENDED]

4. The authority citation for part 129 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 1511–1522, 40101, 40103–40105, 40113, 40119, 44701, 44901–44904, 44906, 44912, 44914, 44935–44939, and 48107.

PART 135—[AMENDED]

5. The authority citation for part 135 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 1153, 40101, 40105, 44113, 44701–44705, 44707–44717, 44722, and 45303.

6. Special Federal Aviation Regulation No. 38–2 is amended by removing the words ''June 1, 1995'' in the last paragraph, and by adding in their place the words ''June 1, 1996.''

Issued in Washington, DC, on May 31, 1995.

David R. Hinson,

Administrator.

[FR Doc. 95–13708 Filed 5–31–95; 4:05 pm]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Oxytetracycline Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a hybrid new animal drug application (NADA) filed by Cross Vetpharm Group Ltd. The NADA

provides for the use of oxytetracycline injection in cattle and swine for the treatment of diseases caused by oxytetracycline susceptible organisms.

EFFECTIVE DATE: June 6, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, has filed ANADA 200–117 (hybrid application) which provides for use of oxytetracycline injection as follows: (1) Intramuscular or intravenous use in beef and nonlactating dairy cattle for the treatment of pneumonia and shipping fever associated with *Pasteurella* spp. and *Hemophilus* spp.; infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresi*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline; (2) intramuscular use in swine for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*; pneumonia caused by *P. multocida*; and leptospirosis caused by *L. pomona*; and (3) intramuscular use in sows for control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

The data submitted in support of this hybrid NADA satisfy the requirements of section 512(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(b)(1) and (b)(2)) and 21 CFR part 514 of the regulations. The hybrid NADA has been defined in the Center's Seventh Generic Animal Drug Policy Letter, dated March 20, 1991. The hybrid application relies on the approval of a listed (pioneer) animal drug and contains additional data needed to support the change in the generic product. The hybrid applicant is thus relying on the approval of the listed animal drug to the extent that such reliance is allowed under section 512(n) of the act, to establish the safety and effectiveness of the active ingredient. An application that relies in part on the approval of a listed animal drug is, for this purpose, considered an application described in section 512(b)(2).

Cross Vetpharm Group Ltd.'s ANADA 200–117 for oxytetracycline injection (Oxy-Shot™ LA) is approved as a generic copy of Pfizer's NADA 113–232 for oxytetracycline injection (Liquamycin® LA–200). The ANADA is approved as of April 13, 1995, and the regulations are amended in 21 CFR 522.1660(b) and (c)(2)(iii) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Additionally, the regulations are amended in 21 CFR 510.600(c) to add Cross Vetpharm Group Ltd. to the list of sponsors of approved applications.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Because this hybrid NADA is reviewed in part as an application under section 512(b)(1) of the act, the hybrid application is eligible for 3 years of exclusivity under section 512(c)(2)(F)(iii) of the act. Under section 512(c)(2)(F)(iii) of the act, this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning on April 13, 1995, because the supplemental application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant.

Under the center's supplemental approval policy (21 CFR 514.106(b)(2)(ii)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Cross Vetpharm Group Ltd.'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''061623'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	061623
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
061623	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.
* * * * *	

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.1660 [Amended]

4. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (b) by removing the phrase ''000010, 000069, and 059130'' and adding in its place

''000010, 000069, 059130, and 061623'', and in paragraph (c)(2)(iii) by revising the last sentence to read ''Discontinue treatment at least 42 days prior to slaughter when provided by 000010 and 28 days prior to slaughter when provided by 000069, 059130, or 061623.''

Dated: May 26, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–13707 Filed 6–5–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 886

RIN 1029–AB72

Abandoned Mine Reclamation Grant Procedures

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; correction.

SUMMARY: This document contains corrections to the final regulations which were published Wednesday, February 22, 1995, (60 FR 9974). The regulations related to State grant closeout reports.

EFFECTIVE DATE: June 6, 1995.

FOR FURTHER INFORMATION CONTACT: Norman J. Hess, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue NW., Washington, DC 20240; Telephone: 202–208–2949.

SUPPLEMENTARY INFORMATION: Both the preamble to the proposed rule published on November 8, 1993 (58 FR 59334), and the preamble to the final rule advised that a revised paragraph 886.23(b) would be added to § 886.23 which would require, at the completion of a grant, agency submission of closeout reports as specified by OSM. Specifically, paragraph 886.23(b) required submission of Form OSM–76 upon project completion. This submission was deemed necessary to comply with the requirement in section 403(c) of the Surface Mining Control and Reclamation Act of 1977, Public Law 95–87, as amended, that on a regular basis OSM note on its inventory those projects completed under Title IV. However, paragraph 886.23(b) of the final rule language was inadvertently published without the reference to ''upon project completion.'' The purpose of this document is to reiterate the intent of the regulation which is that Form OSM–76 and any other closeout reports be filed upon project completion, and to correct paragraph 886.23(b) to include the phrase ''upon project completion.''

Accordingly, the publication on February 22, 1995, of the final regulations which were the subject of FR Doc. 95–4259, is corrected as follows:

§ 886.23 [Corrected]

Paragraph 1. On page 9983, in the first column, in § 886.23, paragraph (b), line one, the words ''At the completion of each grant'' is corrected to read ''Upon project completion.''

Dated: May 30, 1995.

Bob Armstrong,

Assistant Secretary, Land and Minerals Management.

[FR Doc. 95–13772 Filed 6–5–95; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD09–93–009]

RIN 2115–AE46

Special Local Regulations; Macomb Daily Offshore Classic, Lake St. Clair, St. Clair Shores, MI

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing Special Local Regulations for the offshore power boat race, Macomb Daily Offshore Classic (formerly Quake On The Lake). This event will be held on Lake St. Clair, St. Clair Shores, MI, Saturday, May 20, 1995, and thereafter annually on the third weekend in May on Lake St. Clair between Masonic Boulevard and Point Huron. This event will have an estimated 30 high performance power boats racing a closed course race on Lake St. Clair which could pose hazards to navigation in the area. Special Local Regulations which would restrict vessel traffic in the area are necessary to ensure the safety of life, limb and property on portions of Lake St. Clair during this event.

EFFECTIVE DATE: July 6, 1995.

FOR FURTHER INFORMATION CONTACT: Marine Science Technician Second Class Jeffrey M. Yunker, Ninth Coast Guard District, Aids to Navigation and Waterways Management Branch, Room 2083, 1240 East Ninth Street, Cleveland, Ohio, 44199–2060, (216) 522–3990.

SUPPLEMENTARY INFORMATION:

Drafting Information

The drafters of this notice are Lieutenant Junior Grade Byron D. Willeford, Project Officer, Ninth Coast Guard District, Aids to Navigation and Waterways Management Branch, and Lieutenant Karen E. Lloyd, Project Attorney, Ninth Coast Guard District Legal Office.

Regulatory History

On June 3, 1993, the Coast Guard published a notice of proposed rulemaking entitled Special Local Regulations, Quake on the Lake, Lake St. Clair, St. Clair Shores, MI in the **Federal Register** (58 FR 31488). The deadline for the submission of comments was July 19, 1993. The Coast Guard received no letters commenting on the proposal. A public hearing was not requested and one was not held. The Commander, Ninth Coast Guard District has decided to publish the final rule as proposed.

Background and Purpose

On April 4, 1995, the Lake St. Clair Offshore Racing Association submitted an Application for Approval of Marine Event for the Macomb Daily Offshore Classic. The sponsor held this event on August 8, 1993, as the ''Quake on the Lake''. A Notice of Proposed Rulemaking was published for this event and no comments were received. The only changes to this event are the name and date it is being held.

Federalism Implications

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard is conducting an environmental analysis for this event pursuant to section 2.B.2.c of Coast Guard Commandant Instruction M16475.1B, and the Coast Guard Notice of final agency procedures and policy for categorical exclusions found at (59 FR 38654; July 29, 1994).

Economic Assessment and Certification

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review